



## Guidelines for new registration of pharmaceutical firms for supply of medical stores to Konkan Railway

**Registration:** The registration of drug manufacturing firms will be processed by the office of the Executive Director Health Service (EDHS). Extant instructions and procedures for registration of new firms will be followed. EDHS may insist that the firms seeking registration may submit documents such as certificates of good manufacturing practice (GMP), certificates as per the standards laid down by World Health Organisation or ISO 9000 certificate etc. Registration of a firm by one particular zone of INDIAN RAILWAY will not automatically entitle its registration in other zones also, as the firm may/may not have the capacity to supply the material. Registration for supply of certain specified items only may be accorded based on requirements and needs. Registration need not be construed as a blanket registration.

### The following conditions/documents would be mandatory for registration.

1. **Registration fee of ₹5000/- for 3 yrs.**
2. The Pharmaceutical firms must have Annual Turnover of more than 50crores each year and should have at least 5years of standing in the manufacture and marketing of the drug. The firms with more than 50crores seeking registration preferably should also be registered with Indian Railways.
3. Copy of Manufacturing License issued by Local Regulatory authority.
4. Non Conviction Certificate issued by Licensing Authority.
5. WHO-GMP certificate issued to the manufacturer GMP standards met for past 2 years.
6. List of Manufacturing and QC equipment to demonstrate that necessary capability exists to manufacture products and adhering to specifications.
7. ISO-9000 certificate.
8. Installed capacity/utilized during past 2 years. Certificate of CA.
9. Audited financial statement for the last three fiscal years.
10. All products to comply with IP/USP/BP Pharmacopeia standards.
11. Product samples and certificate of Analysis-indented products.
12. Income Tax clearance certificate.
13. Product specification as well as packaging specifications for the items.
14. Samples for packaging components specially label, foil, PVC film or other printed components.
15. Manufacturer should have produced at least 20% of product offered during last two years.
16. Packing offered should be such as to withstand rough handling, transportation and exposure to extreme temperature and climatic conditions.
17. Purchaser reserves the right to visit manufacturing facility.
18. Quality control will be checked and decided by Medical Officer.

Those interested to seek registration with Konkan Railway may kindly deposit a cheque of ₹5000/- (Rupees Five Thousand only) by 30<sup>th</sup> April, 2016 drawn in favour of “FA&CAO Konkan Railway Corporation Limited”

Interested firms can send their application alongwith the registration fee duly completed in all respect at following address:

MEDICAL DEPARTMENT, KONKAN RAILWAY CORPORATION LTD.,  
BELAPUR BHAVAN, PLOT NO.6,  
SECTOR-11, CBD BELAPUR, NAVI MUMBAI 400 614.

Note: Medical Department sends Quotations / Limited Tender Enquiries to Registered Firms by Registered Post.

For details contact Phone No.(022) 27587355/27587356